

C2
correct

which is characterized in that a low-substituted hydroxypropylcellulose having 5% by weight or more to less than 7% by weight of hydroxypropoxyl group is contained therein.

Please cancel claims 8-12 without prejudice.

REMARKS

I. Amendments

For the purpose of having some claims issue in the present application, Claims 1, 18 and 19 have been amended to recite the limitation that the active ingredient is specifically lansoprazole. Applicants reserve the right to pursue the broader claims in future continuing applications.

Claims 8-12 have been cancelled in view of the above amendment.

II. Rejections under §102(e)

In view of the amendment made above, this rejection is moot and should be withdrawn. The cited Ohno reference does not and can not anticipate the claimed invention since Ohno does not teach or suggest lansoprazole as the active ingredient.

III. Rejections under §103(a)

Ohno et al. is asserted by the Examiner to teach a solid pharmaceutical having fast disintegrability and dissolubility in the oral cavity (Ohno '453, col. 6, lines 59-62).

The Examiner further states that "it is the position of the Examiner that fast disintegrability and dissolubility and applicants invention is substantially equivalent..." (Paper 7, page 2, last paragraph).

This is clearly a statement of the Examiner's personal belief and an improper basis for a rejection under §103(a). The Examiner has asserted "substantially equivalent" as his personal conclusion, disregarding the fact that the cited reference does not teach the claimed formulation which is limited to having a low-substituted hydroxypropylcellulose having 5% by weight or more to less than 7% by weight of hydroxypropoxyl group. Ohno et al. do not teach a low-substituted hydroxypropylcellulose having 5% by weight or more to less than 7% by weight of hydroxypropoxyl group.

However, the argument presented by the Examiner is no more than an invitation to experiment, and illustrates the use of improper hindsight in making this rejection. The asserted rejection is clearly improperly based upon the Examiner's personal opinion as to what would have been obvious instead of applying the correct legal standard. The Examiner has clearly failed to evaluate the art as a whole and ignores that which teaches away from the claimed invention. The Examiner has not established a *prima facie* case in support of a finding of non-obviousness.

As stated in the MPEP in accordance with the Law:

Patent Examiners carry the responsibility of making sure that the standard of patentability enunciated by the Supreme Court and by the Congress is applied in each and every case. The Supreme Court in *Graham v. John Deere*, 383 U.S. 1, 148 USPQ 459 (1966), stated:

Under §103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or nonobviousness, these inquiries may have relevancy. . .

This is not to say, however, that there will not be difficulties in applying the nonobviousness test. What is obvious is not a question upon which there is likely to be uniformity of thought in every given factual context. The difficulties, however, are comparable to those encountered daily by the courts in such frames of reference as negligence and scienter, and should be amenable to a case-by-case development. We believe that strict observance of the requirements laid down here will result in that uniformity and definitiveness which Congress called for in the 1952 Act.

Office policy has consistently been to follow *Graham v. John Deere Co.* in the consideration and determination of obviousness under 35 U.S.C. 103. As quoted above, the four factual inquiries enunciated therein as a background for determining obviousness are briefly as follows:

- (A) Determining of the scope and contents of the prior art;
- (B) Ascertaining the differences between the prior art and the claims in issue;
- (C) Resolving the level of ordinary skill in the pertinent art; and
- (D) Evaluating evidence of secondary considerations.

The Supreme Court reaffirmed and relied upon the *Graham* three pronged test in its consideration and determination of obviousness in the fact situations presented in both the *Sakraida v. Ag Pro, Inc.*, 425 U.S. 273, 189 USPQ 449, reh'g denied, 426 U.S. 955 (1976) and *Anderson's-Black Rock, Inc. v. Pavement Salvage Co.*, 396 U.S. 57, 163 USPQ 673 (1969) decisions. In each case, the Court went on to discuss whether the claimed combinations produced a "new or different function" and a "synergistic result," but clearly decided whether the claimed inventions were nonobviousness on the basis of the three-way test in *Graham*.

Nowhere in its decisions in those cases does the Court state that the "new or different function" and "synergistic result" tests supersede a finding of nonobvious or obviousness under the *Graham* test.

Accordingly, examiners should apply the test for patentability under 35 U.S.C. 103 set forth in *Graham*. It should be noted that the Supreme Court's application of the *Graham* test to the fact circumstances in *Ag Pro* was somewhat stringent, as it was in *Black Rock*. Note *Republic Industries, Inc. v. Schlage Lock Co.*, 592 F.2d 963, 200 USPQ 769 (7th Cir. 1979). The Court of Appeals for the Federal Circuit stated in *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1540, 218 USPQ 871, 880 (Fed. Cir. 1983) that a requirement for "synergism" or a "synergistic effect" is nowhere found in the statute, 35 U.S.C. When present, for example in a chemical case, synergism may point toward nonobviousness, but its absence has no place in evaluating the evidence on obviousness. The more objective findings suggested in *Graham*, supra, are drawn from the language of the statute and are fully adequate guides for evaluating the evidence relating to compliance with 35 U.S.C. §103. *Bowser Inc. v. United States*, 388 F. 2d 346, 156 USPQ 406 (Ct. Cl. 1967).

When applying 35 U.S.C. 103, the following tenets of patent law must be adhered to:

- (A) The claimed invention must be considered as a whole;
- (B) The references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination;
- (C) The references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention and
- (D) Reasonable expectation of success is the standard with which obviousness is determined.

Hodosh v. Block Drug Co., Inc., 786 F.2d 1136, 1143 n.5, 229 USPQ 182, 187 n.5 (Fed. Cir. 1986).

(See *The MPEP* v7r1 §2141).

In making the present rejection under §103, the Examiner has failed to follow the proscribed Patent Office policy, and has failed to make any findings upon which the *Graham* factors can be applied to the claimed invention. As such, the Examiner's rejection clearly fails to make a *prima facie* case for a rejection under §103.

The Examiner's analysis is clearly faulty, and fails to consider the art as a whole in comparison to the claimed invention considered as a whole. The Examiner's personal opinion cannot be substituted for the lack of motivation or suggestion in the cited art. There must be some suggestion or teaching in the cited art itself for making the asserted combination. *In re Geiger* 815 F.2d 686, 2 USPQ2d 1276 (CAFC 1987). Only the suggestion of the Examiner, using the teaching of the present invention as a guide, prompts the asserted combination of art. This is an improper use of hindsight to reconstruct the claimed invention from the art without proper motivation being found in the asserted art itself. The Examiner has failed to cite any motivation or teaching in the cited art to make the asserted combination of art, or which would support the asserted rejection.

The Examiner's rejection amounts to no more than an invitation to experiment, as it is *not suggested or taught* in the asserted art what specific "suitable amount of methacrylate polymer" would result in a useful and effective composition. *Ex parte Obukowicz* 27 USPQ2d 1063 (BPAI 1992). The Examiner's asserted motivation is clearly made in hindsight that clearly relies upon the teaching of the present invention to suggest and teach *what the desirable formulation is*. Hindsight obviousness after the invention has been made is not the test. *In re Carroll* 601 F.2d 1184, 202 USPQ 571 (CCPA 1979).

Furthermore, the Examiner has ignored the legal standard by which obviousness is judged, that one of ordinary skill in the art be used as the guide-post. One of ordinary skill in the art does not require advanced knowledge or degrees. *Dow Chemical Co. v. U.S.* 18 USPQ2d 1652 (Ct. Cls. 1990).

The teaching of Ohno actually contradicts the Examiner's personal conclusion in that the experimental data presented by Ohno et al. (Table 1, 3 and 5) clearly demonstrate that the formulations which include a low substituted hydroxypropyl cellulose are clearly inferior to those formulations that do not include this ingredient, as measured by hardness and buccal dissolution time (Tables 2, 4 and 6).

Thus, one of ordinary skill in the art, at the time of the invention, taking the teaching of the Ohno '453 patent as a whole would not be motivated to create the formulations of the claimed invention, as Ohno et al. teach away from the incorporation of a low-substituted hydroxypropylcellulose having 5% by weight or more to less than 7% by weight of hydroxypropoxyl group. Thus, there is no teaching or suggestion in the cited art to arrive at the claimed invention. Art which give only general guidance and is not specific as to the particular form of the claimed invention and how to achieve it, cannot render claims obvious. *Ex parte Obukowicz* 27 USPQ2d 1063 (BPAI 1992).

The Examiner's conclusion is clearly unfounded and based only upon personal opinion biased by the improper use of hindsight, and ignoring the teaching of the asserted art as a whole. The additional teaching of Shashoua et al. ('909) cannot be used to cure the fatal defect in the Ohno reference since Shashoua et al. only teach formulations that are suitable for parenteral administration ('909, col. 48, lines 33-45). Clearly any suggestion by Shashoua is directed to an area of art that is not relevant to the claimed invention.

Furthermore, the asserted combination of art fails because each reference is directed to substantially different areas of treatment. Ohno et al. is directed towards formulations of erythritol, crystalline cellulose and a disintegrant for fast buccal administration, whereas Shashoua et al. is directed towards conjugates of cis-docosahexaenoic acid and taxanes for treating cell proliferative disorders. The subject and nature of the active ingredients, and the disclosure of the cited art itself does not suggest a combination of the asserted art references in and of themselves. Thus, absent express finding of the source for any suggestion to combine the art, the asserted combination is improper (*Ruiz et al. v. AB Chance Co.*, 57 USPQ2d 1161 at 1166 (Fed. Cir. 2000)).

Thus, the burden remains on the Examiner to make a proper *prima facie case* demonstrating proper *Graham* analysis findings to support the rejection. However, to answer the Examiner's request for data, the specification and examples as demonstrated in the specification show that the claimed preparation which comprises a low-substituted hydroxypropylcellulose having 5% by weight or more to less than 7% by weight of hydroxypropoxyl group, such as LH-33, is remarkably superior to those which comprise other a low-substituted hydroxypropylcellulose such as LH-30 (14.6% by weight), LH-31 (11.0% by weight), LH-32 (8.8% by weight), on the dissolubility and taste (Test Example 1 and Test Example 2 of the Specification).

This rejection must be withdrawn.


IV. Conclusion

Applicants request that the holding of Finality be withdrawn.

Reconsideration of the claims as amended in view of the traverse made above is solicited. Early allowance of the claims is requested. Should the Examiner believe that a conference with applicants' attorney would advance prosecution of this application, he is respectfully requested to call applicants' attorney at (847) 383-3372. In the event that the traverse is deemed not to overcome the Examiner's rejection, entry of the amendments is requested for purpose of Appeal.

Respectfully submitted,

22
Dated: February 20, 2001


Philippe Y. Riesen, Reg. No. 35,657
Mark Chao, Ph.D., Reg. No. 37,293
Attorney for Applicants
Customer No. 23115